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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,217	09/23/2003	Robert W. Esmond	4012.0373-02000	2163
22852	7590	08/30/2004		
EXAMINER				
KIM, VICKIE Y				
ART UNIT		PAPER NUMBER		
1614				

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/669,217	ESMOND ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Vickie Kim	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2 and 8-19 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 2 and 8-19 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date: ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: ____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____.                                    |

***Election/Restrictions***

1. Restriction to one of following inventions is required under 35 U.S.C. 121:
  - I. Claim 2, drawn to a method of treating Alzheimer's disease, in a human, comprising administering to the human in need thereof an effective amount of chromium, classified 424, subclass 655.
  - II. Claims 8-12, drawn to a method of treating Alzheimer's disease, in a human, comprising restricting the metabolizable carbohydrates in the diet of the human to a level which results in lowered serum insulin levels, classified 514, subclass 23 .
  - III. Claims 13-19, drawn to a method of treating Alzheimer's disease, in a human, comprising administering to the human in need thereof an effective amount of an agent(e.g. chromium, insulin-like growth factor, a dopamine agonist or thiazolidinedione) which increases the insulin sensitivity of the human and restricting the metabolizable carbohydrates in the diet of the human to a level , classified 514 or 424, subclass various depending species.

***Define how the inventions are related***

- I. Inventions III and I(or II) are related as combination(i.e. a treatment of alzheimer's disease using method according to group I and II) and subcombination(i.e. a treatment of alzheimer's disease using method according to group I or Group II). Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination(i.e. the treatment of alzheimer's disease using a

agent(e.g.thiazolidinedione and group II) does not require the particulars of the subcombination of group I(i.e. chromium) as self-evidenced by instant claims.

2. Invention I and II are patentably distinct inventions. As self evidenced by the claimed groups, inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

*Election of species*

3. Upon the election of patentably distinct invention, if invention of group III is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

This application contains claims directed to the following patentably distinct species of the claimed invention: chromium, insulin-like growth factor, a dopamine agonist or thiazolidinedione. Because a combination drug is not obvious over a combination drug containing different materials(species) under USC 103, a combination drug is considered to be a patentably distinct over other combination drug.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

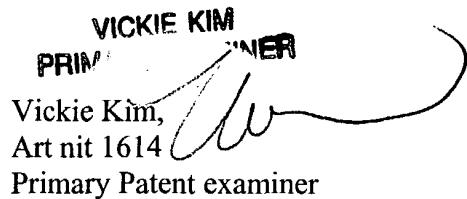
limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

### ***Conclusion***

1. All the pending claims are subject to restriction/election requirement.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

VICKIE KIM  
PRIM<sup>ER</sup>  
Vickie Kim,  
Art Unit 1614  
Primary Patent Examiner

A handwritten signature in black ink, appearing to read "VICKIE KIM" at the top, followed by "PRIM" and "ER" below it. A large, stylized cursive "V" is written across the bottom, with "Vickie Kim," "Art Unit 1614," and "Primary Patent Examiner" written underneath it.